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| APPLICATION NO.                          | FILING DATE    | FIRST NAMED INVENTOR    | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
|------------------------------------------|----------------|-------------------------|-----------------------|------------------|
| 09/767,558                               | 01/22/2001     | Timothy B. Meluch       | ALT-5612 CON of DIV I | 3046             |
| 7.                                       | 590 04/09/2002 |                         |                       |                  |
| Paula Kelly, Esq.                        |                |                         | EXAMINER              |                  |
| Renal Division Baxter International Inc. |                |                         | FORTUNA, ANA M        |                  |
| One Baxter Par<br>Deerfield, IL          |                |                         | ART UNIT              | PAPER NUMBER     |
| ,                                        |                |                         | 1723                  | 9                |
|                                          |                | DATE MAILED: 04/09/2002 |                       |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.

09/767,558

Applicant(s)

Meiuch et al

Advisory Action Exi

Ana Fortuna

1723

Art Unit



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --THE REPLY FILED Mar 12, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. THE PERIOD FOR REPLY [check only a) or b)] a) X The period for reply expires 6 months from the mailing date of the final rejection. b) In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). . Appellant's Brief must be filed within the period set forth in A Notice of Appeal was filed on 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal. The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with 2 requisite fees. 3. The proposed amendment(s) will not be entered because: (a) \( \subseteq \) they raise new issues that would require further consideration and/or search. (See NOTE below); (b) they raise the issue of new matter. (See NOTE below); (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or (d)  $\square$  they present additional claims without cancelling a corresponding number of finally rejected claims. NOTE: Applicant's reply has overcome the following rejection(s): would be allowable if submitted in a 5. Newly proposed or amended claim(s) separate, timely filed amendment cancelling the non-allowable claim(s). The a)  $\square$  affidavit, b)  $\square$  exhibit, or c)  $\boxtimes$  request for reconsideration has been considered but does NOT place the application in condition for allowance because: the claims has not been amended, and prior art still read in claims limitations. 7. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection. For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any): Claim(s) allowed: Claim(s) objected to: Claim(s) rejected: 1-18 9.  $\square$  The proposed drawing correction filed on a)  $\square$  has b)  $\square$  has not been approved by the Examiner. 10. Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11. X Other:see attached respose to arguments.

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## Response to Arguments

1. Applicant's arguments and Affidavit filed on 3/12/02 have been fully considered but they are not persuasive. The affidavit of Mr. Sternberg refers to limitations that are not clearly provided in the "product" claims, e.g. **asymmetric** membrane. The method of making the membrane have been also argued. In determining the allowability of the product claim (or membrane), the membrane structure and properties evaluated, and not the process steps involved in the process of making the membrane. In re Bridgefor, 357 F2d 679; 149 USPQ 55 (CCPA 1966).

The membrane is claimed(Claim 1), as having a structure that is **homogeneous**, and **uniform**; the membrane of Pemawansa (5,279,739) can be considered homogeneous, e.g. is made from the same polymer mixture, and each section of the membrane contributes its substantially proportional share to the permeability characteristics (as defined in Applicant's specification, page 7, first paragraph), and uniform, through at least the ultrafiltration porous skin. Applicant's define the membrane, in specification page 4, second paragraph, as having "uniform structure **throughout the thickness dimension of the membrane**, however this limitation is not in the claims. Uniform porosity structure is also not claimed. Therefore, the rejection is maintained.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ana Fortuna whose telephone number is (703) 308-3857. The examiner can normally be reached on Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310 for regular responses, and (703)872-9311 for after finals.

Ana Fortuna

April 04, 2002

ANA FORTUNA PRIMARY EXAMINER